Handbook of PHARMACEUTICAL EXCIPIENTS

Second Edition



Edited by **Ainley Wade** and **Paul J Weller**

The Property of Steme, Kessler, Goldstein & Fox, P.L.L.C.

American Pharmaceutical Association Washington

The Pharmaceutical Press London

1994

1

© Copyright 1986, 1994 by the American Pharmaceutical Association, 2215 Constitution Avenue NW, Washington, DC 20037-2985, USA, and The Pharmaceutical Press, Royal Pharmaceutical Society of Great Britain, 1 Lambeth High Street, London, SE1 7JN, England.

A catalogue record for this book is available from the British Library.

Library of Congress Catalog Card Number: 94–79492.

International Standard Book Number (ISBN) in the UK: 0 85369 305 6 International Standard Book Number (ISBN) in the USA: 0 91730 66 8

No part of this publication may be reproduced or transmitted in any form or by any means, electronic or mechanical, including photocopy, recording, or any information storage or retrieval system, without prior written permission from the joint publishers.

Typeset in Great Britain by Alden Multimedia, Northampton. Printed and bound in Great Britain by

Dextrose

1. Nonproprietary Names

BP: Glucose PhEur: Dextrosum (glucosum) monohydricum USP: Dextrose

2. Synonyms

Blood sugar; *Caridex*; corn sugar; D-(+)-glucopyranose monohydrate; grape sugar; starch sugar; *Tabfine D-100*.

3. Chemical Name and CAS Registry Number

D-(+)-Glucose monohydrate [5996-10-1] *See also* Section 18.

4. Empirical Formula Molecular Weight

 $C_6H_{12}O_6.H_2O$ See also Section 18. 198.17 (for monohydrate)

5. Structural Formula



Anhydrous material shown.

6. Functional Category

Tablet and capsule diluent; therapeutic agent; tonicity agent; sweetening agent.

7. Applications in Pharmaceutical Formulation or Technology

Dextrose is widely used in solutions to adjust tonicity and as a sweetening agent. Dextrose is also used as a direct compression tablet diluent and binder, primarily in chewable tablets. Although comparable as a tablet diluent to lactose, tablets produced with dextrose monohydrate require more lubrication, are less friable and have a tendency to harden.⁽¹⁻³⁾ The mildly reducing properties of dextrose may be used when tableting to improve the stability of active materials which are sensitive to oxidation.

Dextrose is also used therapeutically and is the preferred source of carbohydrate in parenteral nutrition regimens.

8. Description

Dextrose occurs as odorless, sweet-tasting, colorless crystals or as a white crystalline or granular powder.

9. Pharmacopeial Specifications

Test	PhEur 1983	USP XXII
Identification	+	+
Color of solution	+	+
Specific rotation	$+52.5^{\circ}$ to $+53.3^{\circ}$	$+52.5^{\circ}$ to $+53.5^{\circ}$
Acidity	+	+
Water	7.5-9.5%	7.5-9.5%
(for monohydrate)		

Continued		
Test	PhEur 1983	USP XXII
Residue on ignition	≤ 0.1%	≤ 0.1%
Chloride	≤ 125 ppm	$\leqslant 0.018\%$
Sulfate	≤ 200 ppm	≤ 0.025%
Arsenic	≤ 1 ppm	≤ 1 ppm
Barium	≤ 1 ppm	
Calcium	≤ 200 ppm	_
Heavy metals	·	≤ 5 ppm
Lead	≤ 0.5 ppm	
Dextrin	+	+
Soluble starch, and sulfites	+	+

SEM: 1.

Excipient: Dextrose anhydrous (granular) Manufacturer: Mallinckrodt Speciality Chemicals Co Lot No.: KLKZ Magnification: 180x



10. Typical Properties

Data for dextrose monohydrate shown, see Section 18 and HPE Data for dextrose anhydrous data.

Acidity/alkalinity:

pH = 3.5-5.5 (20% w/v aqueous solution)

Compressibility: see HPE Data.

Density: 1.54 g/cm³

Flowability: see HPE Data.

Heat of solution: 105.4 J/g (25.2 cal/g)

Hygroscopicity: anhydrous dextrose absorbs significant amounts of moisture at 25°C and a relative humidity of about 85% to form the monohydrate. The monohydrate similarly only absorbs moisture at around 85% relative humidity and 25°C. See HPE Data.

Melting point: 83°C

Osmolarity: a 5.51% w/v aqueous solution is iso-osmotic with serum. However, it is not isotonic since dextrose can pass through the membrane of red cells and cause hemolysis.